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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Furth et al.

Application No. 10/037,616

Filed: January 2, 2002

Art Unit: 1636

Examiner: J. Ketter

For: TARGETING GENE EXPRESSION TO LIVING TISSUE USING JET INJECTION

AMENDMENTS TO CLAIMS MADE IN RESPONSE TO OFFICE ACTION DATED NOVEMBER 6, 2002

Amendments to existing claims:

1. A method [of] for obtaining [targeting a] transient gene expression [and] or stable gene expression in somatic cell tissue comprising: [by] exogenously administering a plasmid expression vector to differentiated somatic cell tissue selected from the group consisting of skin, muscle, fat and mammary tissue of a living organism[s], [through] using a jet injector [technique], wherein said plasmid expression vector is expressed in [a] the living organism.

2. A method according to claim 1 further involving the steps of a member selected from the group consisting of (a) ablation of malignant cells, (b) ablation of cells infected with specific viruses, [(c) gene therapy,] ([d] c) immunization, ([e] d) generation of [transgenic] chimeric organisms, ([f] e) converting secretory cells of living organisms [into bio-reactors for producing] to produce a protein, ([g] f) modifying the expression of endogenous gene, ([h] g) providing a means for studying the effects of specific proteins in differentiated and undifferentiated tissue, ([I] h) generating an animal model system for human diseases, and ([j] i) inducing wound healing via the production of specific growth factor genes.

3. A method according to claim 2 wherein the secretory cells of the living organism are mammary or bladder cells.

4. A method according to claim 1 wherein said plasmid expression vector comprises DNA sequences selected form the group consisting of a DNA sequence claiming enhancer/[promotor] promoter and other regulatory elements, a DNA sequence which can be transcribed into an RNA which RNA can be (a) translated into a protein, (b) includes a transcriptional termination signal, and (c) may include coding sequences for a signal peptide which allows a protein to be exported from the cell, a DNA sequence which targets a gene for incorporation into the genome, a DNA sequence which directly replicates in eukaryotic cells, and a plasmid sequence which allows DNA replication in prokaryotic cells.

5. A method according to claim 4 wherein said DNA sequence is constructed using an enhancer/promoter component[s], a termination signal[s], and a signal peptide [coating] coding sequence[s] from different genes which are combined to directly express in a specific manner.

6. A method according to claim 2 wherein the enhancer/promoter sequence is a naturally occurring [element such as the HCMVIE1] promoter/enhancer[, or the enhancer/promoter sequences constructed using specific DNA elements which mediate binding by specific transcription factors to directly express only in specific cell types].

7. A method according to claim 4 wherein the enhancer/promoter is composed of a generic TATA box and binding sites [cites] for the E2 transcription factor and said enhancer/promoter is coded by the papillomavirus genome, wherein said enhancer/promoter is expressed in cells capable of expressing the E2 protein from papillomavirus.

8. The method of claim 1, wherein said differentiated tissue is selected from the group consisting of muscle, fat and mammary tissue.

9. The method of claim 1, wherein said plasmid expression vector comprises a promoter-enhancer sequence selected from the group consisting of human cytomegalovirus immediate early gene 1 and whey acidic protein promoter sequence.

10. The method of claim 1, wherein said plasmid expression vector comprises a hybrid gene selected from the group consisting of human cytomegalovirus immediate early gene 1 and chloramphenicol acetyl transferase gene; whey acidic protein promoter sequence and chloramphenicol acetyl transferase gene; and human cytomegalovirus immediate early gene 1 and β-galactosidase gene.

11. The method of claim 1, wherein said plasmid expression vector is expressed in a living organism at about 1 to about 3 cm[.] [D]distant from the site of injection

12. The method of claim 1, wherein said plasmid expression vector comprises supercoiled DNA fragments of 1 microgram/microliter in 1 mM TRIS - .1 mM EDTA and is administered in volumes between 100 microliters and 500 microliters per injection.

13. Canceled

14. Canceled

15. Canceled

16. Canceled

17. Canceled

18. Canceled

19. A method [of] for obtaining [targeting] transient gene expression [and] or stable gene expression in mammary tissue comprising: [by] exogenously administering a plasmid expression vector, to mammary tissue of a living organism[s], [through] using a jet injector [technique], wherein said plasmid expression vector is expressed in [a] the living organism.

20. A method according to claim 1, wherein said living organism is immunized by said plasmid expression vector which is expressed in said living organism.

21. A method of immunization comprising the steps of jet injecting an effective amount of a plasmid expression vector, to transform differentiated somatic cell tissue of a living organism[s] selected from the group consisting of skin, muscle, fat and mammary tissue, wherein said plasmid expression vector is expressed in [a] the living organism, and wherein DNA expressed from said plasmid expression vector immunizes said living organism.

22. A method according to claim 2 wherein the enhancer/promoter sequence is the HCMVIE1 promoter/enhancer sequence.

23. A method according to claim 2 wherein the enhancer/promoter sequence is an enhancer/promoter sequences constructed using specific DNA elements, which mediate binding by specific transcription factors to directly express only in specific cell types.